Notice of Allowability	Application No. 09/973,278	Applicant(s) FISCHER ET AL.	
	Examiner Alexander H. Spiegler	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Applicants' After-final response, filed on February 27, 2004*.

2. ☒ The allowed claim(s) is/are *25-70*.

3. ☒ The drawings filed on *10 October 2001* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *3/5/04* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it must be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's amendment was given in a telephone interview with Janet Martineau on March 5, 2004.

Please amend the specification as follows:

On page 4, line 7, before "Detailed Description", insert --

Brief Description of the Several Views of the Drawing(s)

Figures 1(A)-(C) show the nucleotide sequence (SEQ ID NO: 32) and deduced amino acid sequence (SEQ ID NO: 172) corresponding to Gene No: 22. --.

On page 74, line 3 to page 75, line 14, please make the following changes:

~~Figure 2~~ Table 6 shows an analysis of the amino acid sequence (SEQ ID NO: 172). Alpha, beta, turn and coil regions; hydrophilicity and hydrophobicity; amphipathic regions; flexible regions; antigenic index and surface probability are shown, and all were generated using the default settings of the recited computer ~~algorithyms~~algorithms. In the "Antigenic Index or Jameson-Wolf" graph, the positive peaks indicate locations of the highly antigenic regions of the protein, i.e., regions from which epitope-bearing peptides of the invention can be obtained.

Polypeptides comprising, or alternatively consisting of, domains defined by these graphs are contemplated by the present invention, as are polynucleotides encoding these polypeptides.

~~The data presented in Figure 2 are also represented in tabular form in Table 6.~~ The columns in Table 6 are labeled with the headings "Res", "Position", and Roman Numerals I-XIV. The column headings refer to the following features of the amino acid sequence presented in ~~Figure 2, and~~ Table 6: "Res": amino acid residue of SEQ ID NO:172 and Figures 1A-C; "Position": position of the corresponding residue within SEQ ID NO:172 and Figures 1A-C; I: Alpha, Regions - Garnier-Robson; II: Alpha, Regions - Chou-Fasman; III: Beta, Regions - Garnier-Robson; IV: Beta, Regions - Chou-Fasman; V: Turn, Regions - Garnier-Robson; VI: Turn, Regions - Chou-Fasman; VII: Coil, Regions - Garnier-Robson; VIII: Hydrophilicity Plot - Kyte-Doolittle; IX: Hydrophobicity Plot - Hopp-Woods; X: Alpha, Amphipathic Regions - Eisenberg; XI: Beta, Amphipathic Regions - Eisenberg; XII: Flexible Regions - Karplus-Schulz; XIII: Antigenic Index - Jameson-Wolf; and XIV: Surface Probability Plot - Emini.

Preferred embodiments of the invention in this regard include fragments that comprise, or alternatively consisting of, one or more of the following regions: alpha-helix and alpha-helix forming regions ("alpha-regions"), beta-sheet and beta-sheet forming regions ("beta-regions"), turn and turn-forming regions ("turn-regions"), coil and coil-forming regions ("coil-regions"), hydrophilic regions, hydrophobic regions, alpha amphipathic regions, beta amphipathic regions, flexible regions, surface-forming regions and high antigenic index regions. The data representing the structural or functional attributes of the protein set forth in ~~Figure 2 and/or~~ Table 6, as described above, was generated using the various modules and algorithms of the DNA*STAR set on default parameters. In a preferred embodiment, the data presented in columns VIII, IX, XIII, and XIV of Table 6 can be used to determine regions of the protein which exhibit a high degree of potential for antigenicity. Regions of high antigenicity are determined from the data presented in columns VIII, IX, XIII, and/or XIV by choosing values which represent regions of the polypeptide which are likely to be exposed on the surface of the polypeptide in an environment in which antigen recognition may occur in the process of initiation of an immune response.

Certain preferred regions in these regards ~~are set out in Figure 2, but~~ may, as shown in Table 6, be represented or identified by using tabular representations of the data ~~presented in Figure 2~~. The DNA*STAR computer algorithm ~~used to generate Figure 2 (set on the original default~~

~~parameters)~~ was used to present the data ~~in Figure 2~~ in a tabular format (See Table 6). The tabular format of the data ~~in Figure 2~~ is used to easily determine specific boundaries of a preferred region.

EXAMINER'S COMMENT

1. In Applicants' response, filed on February 27, 2004, Applicants' requested clarification regarding the term "solely" as used by the Examiner with respect to the withdrawal of the 35 U.S.C. 101 rejection. Specifically, to satisfy the utility requirement under 35 U.S.C. 101, Applicant need only assert one specific, substantial and credible utility (see MPEP 2107 and the Utility Guidelines). In the instant case, Applicants have clearly established that the claimed protein has at least a single specific, substantial and credible utility, as it induces IL-10 production. Accordingly, because Applicants have demonstrated a specific, substantial and credible utility, the utility inquiry is complete and the 101 rejection was withdrawn.

2. Applicant is now required to submit a substitute declaration or oath to correct the deficiencies set forth in the Notice of Missing Parts, mailed on December 6th, 2001. Specifically, not all of the inventors have signed the declaration. The substitute oath or declaration must be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability" (PTO-37). Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136. Failure to timely file the substitute declaration (or oath) will result in **ABANDONMENT** of the application. The transmittal letter accompanying the declaration (or oath) should indicate the date of the "Notice of Allowance" (PTOL-85) and the application number in the upper right hand corner.

THE FOLLOWING IS AN EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE:

The 35 U.S.C. 112, 1st and 2nd rejections have been withdrawn in view of Applicant's arguments. Specifically, Applicants' stated, "The rejected claims recite "closed" claim language, i.e., in claim 51, the fragment must be a sequence within residues 27 to 111 of SEQ ID NO: 164 and further must be at least 30 contiguous amino acids residues in length...No flanking sequences are encompassed in these claims as the claims recite "closed," i.e., consisting of, claim language". See page 3 of Applicants response. Accordingly, because the claims are drawn to "closed," i.e., consisting of, claim language and do not read on any flanking sequences, the claims are definite, and have adequate written description under 35 U.S.C. 112, 1st and 2nd paragraphs.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (571) 272-0788. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (571) 272-0747. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alexander H. Spiegler
March 8, 2004

CARLA J. MYERS
PRIMARY EXAMINER